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(11) EP 0 894 474 A1

EUROPEAN PATENT APPLICATION

Date of publication:
03.02.1999 Bulletin 1999/05

(51) Int. Cl.[6]: A61B 17/00

Application number: 97112968.9

Date of filing: 28.07.1997

Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

Applicant:
Ischinger, Thomas, Prof. Dr.
81929 München (DE)

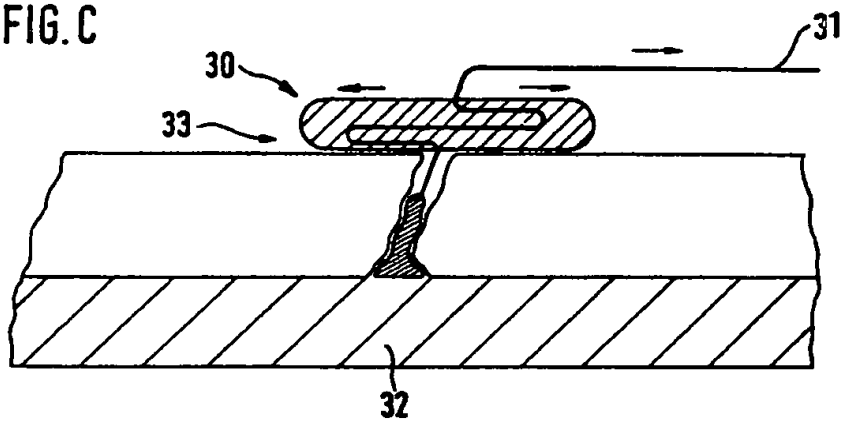
(72) Inventor:
Ischinger, Thomas, Prof. Dr.
81929 München (DE)

(74) Representative:
Ruschke, Hans Edvard, Dipl.-Ing.
Ruschke Hartmann Becker
Pienzenauerstrasse 2
81679 München (DE)

Tension holder e.g. for vascular suture or plug device

The invention relates to a device with a mecha- to exert tension upon a string like element such as ure. The device has its major extension in the plane hich it is positioned and its minor extension along xis of tension exertion. Said tension mechanism oys lateral or spiral displacement of the string like element, wherein the tensile mechanism has elastic (springy) property, and said mechanism is not substantially extending above the upper surface of the device. This device is particularly used in association with a hemostatic plug to which a string is attached.

FIG. C



tion

und:

With the proliferative use of percutaneous vas-erventions such as Percutaneous Transluminal y Angioplasty (PTCA), angioplasty in other than / vessels (PTA), stenting, atherectomy, laser :ain other minimally invasive procedures in car-angiology, cardiosurgery, radiology and surgery as other disciplines, a need for percutaneous devices of the operative entry site or vascular ɜ site has been established.

In particular after percutaneous vascular pro-such as PTCA and PTA a method of nonsurgi-ure with or without a suture of the puncture site ven helpful in reducing bleeding complications, ı the time necessary to mechanically or manu-press the vascular access site until hemostasis ed and recucing the time to patient discharge. r closure devices may reduce hosptalization ı may be helpful in performing catheter guided ieous procedures on a outpatient basis.

However there are still problems associated sure devices, which need to be addressed. Clo-vices that use sutures applied by needles are lys reliable and may need an additional means stasis such as a collagen or other plug on top of cular punture site or in the puncture channel. ıg, however, carries the risk of getting dislodged embolizing into the circulation. This may be a ır risk if repeat procedures have to be carried ugh the same punture channel within hours or a s after the initial procedure. Therefore, closure that employ plugs should be associated with a iechanism to hold the plug in place. Also, often, ded that sutures are being kept under tension for me to safely achieve hemostasis. Therefore, closure devices featuring needles and sutures as vascular closure devices emloying puncture gs need a mechansim to hold the suture under and the plug safely in place in order to improve and safety of the closure device. This applies closure devices used in other minimally invasive itive procedures where (percutaneous) closure may be of advantage. It is irrelevant for the use-of such tension holding device or plug securing whether the plug is located totally or partially in cular lumen or totally or partially in the puncture perative access site channel.

jor feature of such closure device and tension nd / or plug securing device is, that such device t prohibit manual compression upon the punture eeded in case of failure of any of the closure

Some of the closure devices are of such a con-n, that no additional manual or any other ical compression is possible, since the device is ıg significantly above the percutaneous access site (punture site) level. Mechanical compression would critically damage the device and/or inflict trauma to the patient. One solution may be the removal of the part of the device that is extending significantly above the access site level (usually the tension hlding part of the device). However, this carries among other risks e.g.the risk of loosing the plug into the circulation.

[0004] It has been found, that the present invention is solving such shortcomings by describing a closure device with a tension hlding part that is not significantly extending above the access site level and that permits application of manual / other mechanical pressure without the risk of reducing the safety and function of the device and without the risk of traumatizing the accesss site and its surrounding tissue (percutaneous punture site area)

Prior art:

[0005] The vascular puncture site sealing device using a collagen plug commercially exploited under the trade name VASOSEAL by Datascope Corp, USA; the combined plug and intravascular achor device, commercially exploited under the trade name ANGIO-SEAL by Sherwood Davies & Geck, USA and the suture devices by Perclose Inc, USA. (including Int application Nr WO 95/13021 and WO 94/13211)
Other prior art includes the device description by Howard Taymor-Luria,USA (US patent 5415657) and by Gene Myers (US patent 5486195); and the international patent applications by David Hathaway et al (Int publication Nr WO 94/08516). These description deal with the use of closure devices and do not describe a suture tension device and/or plug securing device. However, in particular with use of the ANGIO SEAL device, a plug securing and suture tension holding device that conforms to the practical needs is a necessity.

[0006] Any description of the present invention will focus on vascular closure devices as they are primarily used after vascular catheterization procedures, yet the description is not limited to such uses; any other use such as after endoscopic procedures, in gyecology, gastroenerology are other operative or minimally invasive procedures may also represent areas of use. "A" always means also more than one.

Description of invention:

[0007] Once a collagen plug is placed within a puncture site channel and associated (attached) with a string (suture) or a plug or anchor is placed intravascularly and is pulled against the puncture site hole from outside via a string or suture or if a suture needs continued tension for a period of time in order to bettr achive hemostasis, a device that exerts continued traction upon such string or suture connection is often needed.

[0008] Such tension device will stay in place for minutes, hours or days and will exert the tension while

g positioned at the skin level of the patient at or ınd the percutaneous access site (puncture site). device needs an atraumatic configuration that mines trauma to the tissue it is resting/pushing on. This ırticularly important, since by virtue of the tension device is exerting the device will be pulled against tissue. Also, the device needs to be flat, so that hanical pressure (manual pressure) can be exerted ɔed) on top of the device. So in the preferred configons of the device its diameter in the axis of exertion ınsion (ie nearly perpendicular to the plane of the ıce of the skin) is less than its diameter in the axis ıe plane of the skin. In addition to the flat shape, d or oval type configuration help to adapt the device ıe configurations of its respective positions, e.g. in groin. The side of the device facing the skin may be led for reduced trauma to the tissue and / or lined a special optimally skin/tissue compatible surface.

9] Another embodiement is a a open area of the ɔe, i.e. a central or eccentrically located hole or a slit ıre that accomodates the string or suture in such a that the string or suture can be easily threaded ıgh or into this opening. Once the suture or string nent) upon which the tension is to be exerted is in e, a fixation mechanism is activated in order to both y fix the element in its desired distance from the (one means to select the degree of tension) and ate the tension mechansim located inside the flat e.g. olive shaped device.

0] Commonly the device will be placed just at the level with one hand, while the other hand is maining slight tension on the string. Once the tension fixation mechanism is activated, the device is exertlight tension and both hands can be released.

1] In one embodiement,the tension exerted by the ɔe - which is dependent on the intial tension of the g that had be held manually and the (elastic) propand the thickness of the tissue between the plug or ıuture - may be indicated by a simple gauge on the ide of the device.

2] The mechanism its self consists of a spring hanism that displaces the the string from its sraight se to the side (Bajonett ähnlich) or rolls or partially the string up until a tension limit inside the device. position of the device can be changed; the tension be determined by positioning (selecting the dise to the skin surface) or by selecting a certain ee of tension with the mechanism itsself prior or placement of the device.

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Device with a mechanism to exert tension upon a string like element such as a suture, wherein the device has its major extension in the plane on which t is positioned and its minor extension along the the axis of tension exertion (blunt, flat configuration), said tension mechanism employing a primarily lateral or spiral displacement of the string like element, wherein the tensile mechanism has elastic (springy) property, and said mechanism is not substantially extending above the upper surface of the device, said tensile mechanism being active upon activation from a non tensile to a tensile (functional) state

2. Device of claim 1 wherein the device is flat oval shaped (flat egg)

3. Device of claim one wherein the device is of a disc like flat shape

4. Device of claim 1 wherein the device permits pressure application on top of it without unacceptable trauma to the underlying tissue

5. Device of claim 1, wherein the side of the device facing the tissue (or in contact with the tissue) is of soft material and/ or tissue compatible material

6. Device of claim 1 used in association with a hemostatic plug to which a string is attached

7. Device of claim 1, wherein the strength of the tensile mechanism can be preselected

8. Device of claim 1 wherein the actual degree of tension is indicated by a gauge

9. Device of claim 1 wherein the tensile mechanism and fixation of the position of the device is activated at the same time

10. Device of claim 1, wherein activation of the tensile mechanism can be done by one hand

11. Device of claim 1, wherein the string to be extended is inserted into the device through a central hole of the device

12. Device of claim 1 wherein the string to be extended is inserted into the device through a slit like opening

13. Device of claim 1 wherein the string to be extended is leaving (exiting from the device) the device at least on one side through a central or nearly central hole or slit like hole

FIG. A
Prior Art

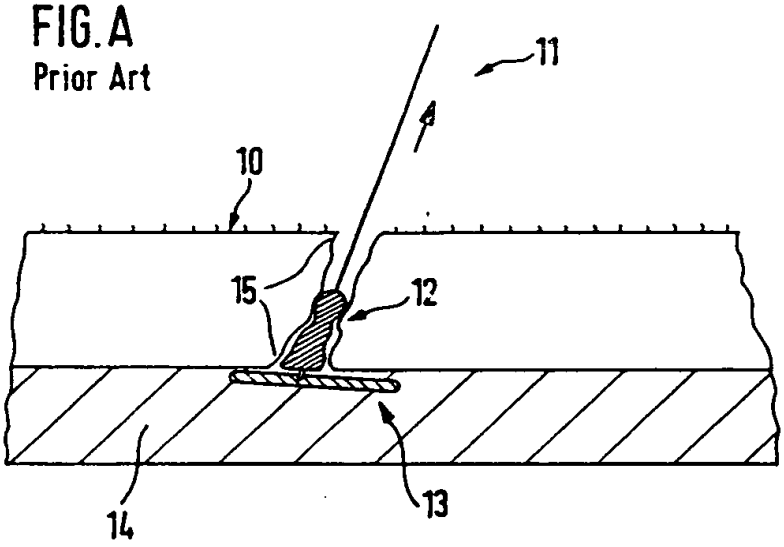


FIG. B
Prior Art

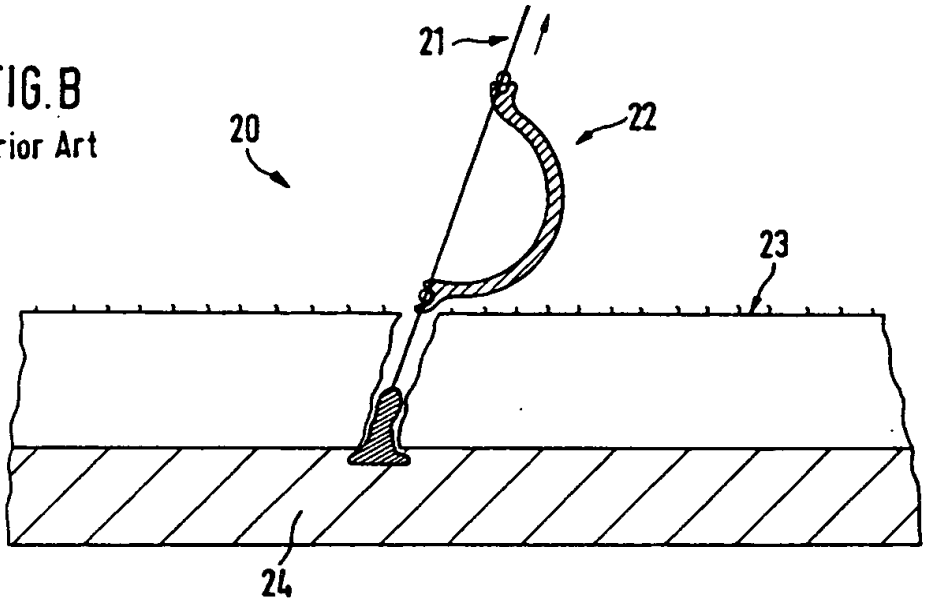


FIG. C

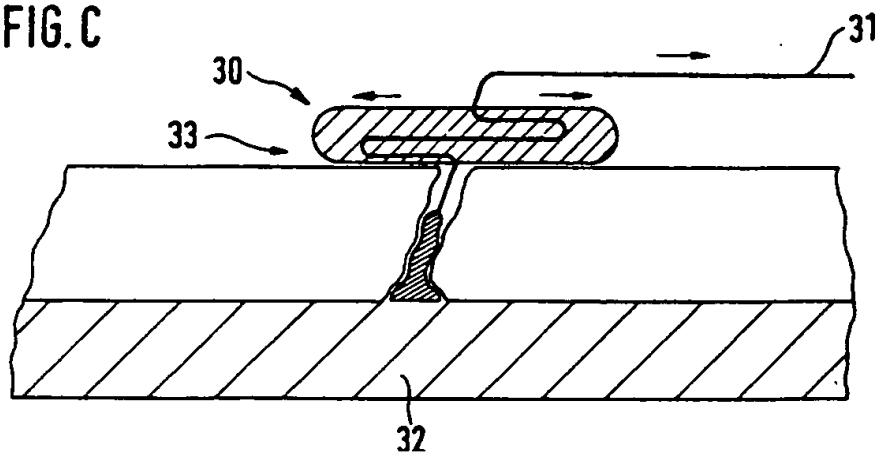


FIG. D

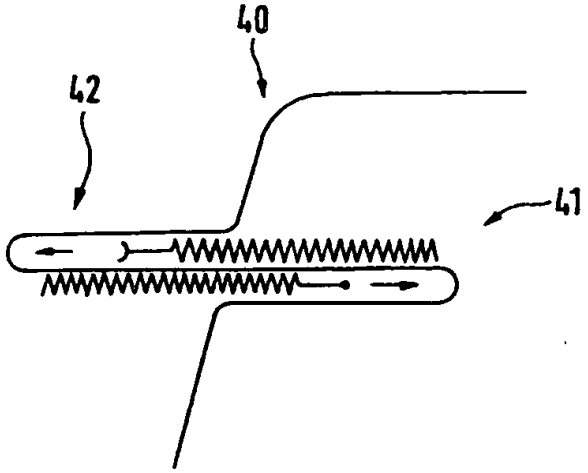


FIG. E_1

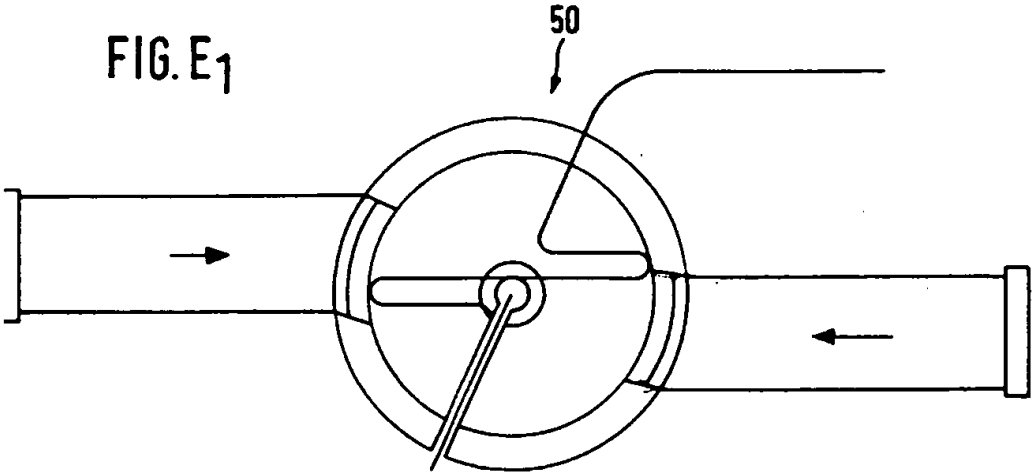
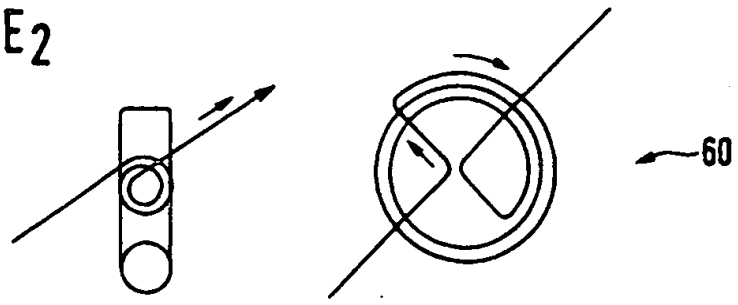


FIG. E_2



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EUROPEAN SEARCH REPORT

Application Number
EP 97 11 2968

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US 4 950 283 A (DZUBOW LEONARD M ET AL) * column 2, line 25 - line 32 *	1	A61B17/00
A	US 5 411 520 A (NASH JOHN ET AL) * column 14, line 58 - line 65 *	1,6	
A	WO 89 11301 A (KENSEY NASH CORP) * page 9, line 5 - line 18 *	1	
A	US 3 650 274 A (EDWARDS LEON C ET AL)		
A	US 4 750 492 A (JACOBS RANDALL W)		
A	DE 19 58 429 A (J. GAECKEL)		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	25 November 1997	Gérard, B

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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